

Claims

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1. A stable protein preparation, wherein the preparation comprises one or more stabilisers selected from the group consisting of non-polar and basic amino acids and wherein the preparation has a pH of 4.2 to 5.4.
2. The preparation of claim 1, wherein the one or more stabilisers are selected from the group consisting of histidine, arginine, lysine, ornithine, isoleucine, valine, methionine, glycine and proline.
3. The preparation of claims 1 or 2, wherein the stabiliser is proline.
4. The preparation of claim 3, wherein proline is L-proline.
5. The preparation of any one of the preceding claims, wherein it has a pH of 4.5 to 5.2.
6. The preparation of claim 5, wherein it has a pH of 4.6 to 5.0.
7. The preparation of any one of the preceding claims, wherein it comprises the stabiliser at a final concentration of at least 0.2 M.
8. The preparation of claim 7, wherein it comprises the stabiliser at a final concentration of 0.2 to 0.4 M.
9. The preparation of claim 8, wherein it comprises the stabiliser at a final

concentration of 0.25 M.

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10. The preparation of any one of the preceding claims, wherein its protein concentration is from 5 to 25 % w/v.
11. The preparation of claim 10, wherein its protein concentration is from 15 to 20% w/v for subcutaneous administration.
12. The preparation of claim 10, wherein its protein concentration is from 6 to 15 % w/v, for intravenous administration.
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13. The preparation of claim 12, wherein its protein concentration is from 8 to 12 % w/v.
14. The preparation of any one of the preceding claims, wherein it is an immunoglobulin preparation.
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15. The preparation of any one of the preceding claims, wherein it is an IgG, IgA or IgM preparation.
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16. A pharmaceutical composition comprising the protein preparation of one of the preceding claims and pharmaceutically acceptable additives.
17. The pharmaceutical composition of claim 16, wherein it comprises the immunoglobulin preparation of any one of claims 11 to 15 for a dosage of 0.2 to 2.0 g immunoglobulin per kg bodyweight per day.
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18. A method of stabilising protein preparations, in particular immunoglobulin preparations, comprising providing an aqueous protein solution and adding one or more stabilisers selected from the group consisting of basic and non-polar amino acids, wherein the pH of the solution is adjusted to a pH of about 4.2 to 5.4.
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19. The method of claim 18, wherein the stabiliser is selected from the group consisting of histidine, arginine, lysine, ornithine, isoleucine, valine, methionine and proline.
- 5 20. The method of claim 18 or 19, wherein the pH is adjusted to 4.8.
21. The method of any one of claims 18 to 20, wherein the final stabiliser concentration is adjusted to 0.2 to 0.4 M.